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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/812,780   | 03/29/2004  | Yiwen Tang           | 50623.280           | 5001             |
| 7590   | 07/11/2007  |                      | EXAMINER            |                  |
| Cameron Kerrigan<br>Squire, Sanders & Dempsey L.L.P.<br>Suite 300<br>One Maritime Plaza<br>San Francisco, CA 94111 |             |                      | FISHER, ABIGAIL L   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1609                |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 07/11/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 10/812,780                 | TANG ET AL.      |
|                              | Examiner<br>Abigail Fisher | Art Unit<br>1609 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 29 March 2004.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-27 are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

**Claims 1-27 are pending.**

### ***Restrictions/Elections***

Applicant is required to elect a species from each of the following 3 species election requirements.

#### **First Species Election Requirements**

Applicant is required to elect a single biocompatible polymeric moiety (Group 1) and a single structural polymeric moiety (Group 2). Alternatively the applicant can elect a single AB block-copolymer (Group 3).

Therefore Applicant is required to elect a single species from both Group 1 and Group 2 or a single species from the Group 3.

#### **Group 1**

**Applicant must elect a single biocompatible polymeric moiety.**

Claims 1-3, 5-7, 9, 13-20, 22, and 26 are generic to the following disclosed patentably distinct species: poly(alkylene glycol), poly(2-hydroxyethyl methacrylate), poly(3-hydroxypropyl methacrylamide), hydroxylated poly(vinyl pyrrolidone), sulfonated dextran, sulfonated polystyrene, fibrin, fibrinogen, cellulose, starch, collagen, hyaluronic

acid, heparin, a graft copolymer of poly(L-lysine)-graft-co-poly(ethylene glycol), and copolymers thereof.

**Group 2**

**Applicant must elect a single structural polymeric moiety.**

Claims 1-3, 5-7, 9, 13-20, 22, and 26 are generic to the following disclosed patentably distinct species: poly(D,L-lactide), poly(caprolactone), poly(caprolactone-co-D,L-lactide), poly(butylene terephthalate), poly(ester amide), poly(aspirin), poly(L-lactide), poly(glycolide), poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(3-hydroxybutyrate), poly(4-hydroxybutyrate), poly(hydroxyvalerate), poly(3-hydroxybutyrate-co-valerate), poly(4-hydroxybutyrate-co-valerate), and polydioxanone.

**Group 3**

**Applicant must elect a single AB block-copolymer**

Claims 1-3, 5-7, 9, 13-20, 22, and 26 are generic to the following disclosed patentably distinct species: poly(ethylene-glycol)-block-co-poly(caprolactone) and poly(ethylene-glycol)-block-co-poly(butylene terephthalate).

**A proper response would be one in which the applicant elects one species from Group 1 and Group 2 or elects one species from Group 3.**

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at

the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### **Second Species Election Requirements**

**Applicant is required to elect a single second polymer moiety.**

Claims 1-2, 4, 11, 13-14, 17, 26 and 27 are generic to the following disclosed patentably distinct species: poly(L-lactide), poly(D,L-lactide), poly(glycolide), poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(caprolactone), poly(L-lactide-co-caprolactone), poly(D,L-lactide-co-caprolactone), polyhydroxyalkanoates, poly(3-hydroxybutyrate), poly(4-hydroxybutyrate), poly(hydroxyvalerate), poly(3-hydroxybutyrate-co-valerate), poly(4-hydroxybutyrate-co-valerate), poly(ester amides),

poly(anhydrides), poly(carbonates), poly(trimethylene carbonate-co-glycolide), poly(trimethylene carbonate-co-L-lactide), poly(trimethylene carbonate-co-D,L-lactide), poly(dioxanone), poly(phosphazenes), poly(orthoesters), poly(tyrosine-co-carbonates), polyalkylene oxalates, poly(glycerol-co-sebacic acid esters), cyanoacrylates, poly(amino acids), poly(lysine), poly(glutamic acid) and combinations thereof.

A proper response would clearly **elect a single second polymer moiety**.

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a**

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### **Third Species Election Requirements**

**Applicant is required to elect a single biologically degradable polymer.**

Claims 14-15, 24, 26 and 27 are generic to the following disclosed patentably distinct species: poly(L-lactide), poly(D,L-lactide), poly(glycolide), poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(caprolactone), poly(L-lactide-co-caprolactone), poly(D,L-lactide-co-caprolactone), polyhydroxyalkanoates, poly(3-hydroxybutyrate), poly(4-hydroxybutyrate), poly(hydroxyvalerate), poly(3-hydroxybutyrate-co-valerate), poly(4-hydroxybutyrate-co-valerate), poly(ester amides), poly(anhydrides), poly(carbonates), poly(trimethylene carbonate-co-glycolide), poly(trimethylene carbonate-co-L-lactide), poly(trimethylene carbonate-co-D,L-lactide), poly(dioxanone), poly(phosphazenes), poly(orthoesters), poly(tyrosine-co-carbonates), polyalkylene oxalates, poly(glycerol-co-sebacic acid esters), cyanoacrylates, poly(amino acids), poly(lysine), poly(glutamic acid) and combinations thereof.

A proper response would clearly **elect a single biologically degradable polymer.**

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

A proper response would clearly **elect a single biologically degradable polymer.**

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail Fisher whose telephone number is 571-270-3502. The examiner can normally be reached on M-Th 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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*Ardin H. Marschel 7/3/07*  
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SUPERVISORY PATENT EXAMINER